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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,440	04/13/2001	Omar S. Khalil	6800.US.O1	2947

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EXAMINER

KREMER, MATTHEW J

ART UNIT PAPER NUMBER

3736

DATE MAILED: 11/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/834,440

Applicant(s)

KHALIL ET AL.

Examiner

Matthew J Kremer

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) ☐ Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7,8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 6-7, 9-12, 14, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,978,691 to Mills. Mills teaches a device for noninvasively determining oxygen saturation, partial pressure of oxygen, partial pressure of carbon dioxide, concentration of bicarbonate ion and total carbon dioxide, acid-base balance, base excess, hemoglobin level, hematocrit, oxyhemoglobin level, deoxyhemoglobin level, and oxygen content. (Abstract of Mills). Mills teaches the two probes at different locations at two different temperatures are used to calculate oxygen saturation. (column 12, lines 6-42 of Mills). Mills teaches a mathematical relationship (column 9, line 56 to column 11, line 56 of Mills). In regard to claims 1 and 7, the device can be used to detect cancers. (column 14, lines 20-25 of Mills). In regard to claims 2 and 10, 660nm and 940 nm can be used. (Fig. 11 of Mills). In regard to claims 3 and 11, reflectance can be employed, (column 8, lines 1-3 of Mills). In regard to claims 4 and 12, simultaneous measurements can be taken. (column 12, lines 6-22 of Mills). In regard to claims 6 and 14, temperatures ranging from 33-40 °C can be used. (column

12, lines 6-42 of Mills). In regard to claims 9 and 16, the device can be used to determine glucose. (column 13, lines 28-42 of Mills).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills (cited by Applicant) as applied to claims 1 and 9. In regard to claims 5 and 13, Mills does not teach an embodiment in which the two probe locations are taking measurements at different temperatures in a sequential fashion. Mills teaches two probe locations in which measurements are taken at different temperatures simultaneously. (column 12, lines 6-13 of Mills). Mills also teaches a single probe location in which measurements are taken at different temperatures in a sequential fashion. (column 11, lines 59-67 of Mills). Mills is implying that his method does not require that the both measurements at different temperatures are taken simultaneously since one method allows for sequential measurements. This implication would lead to one with ordinary skill in the art to believe that sequential measurements are a valid option if desired due to design considerations. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made

to modify the device with multiple measurement locations to include sequential measurement taking since Mills implies that such a method is valid. In regard to claim 15, Mills does not explicitly teach providing a population comprising a sufficient number of subjects to establish a category selector or to establish a statistically meaningful relationship. Mills teaches the use of normal volunteers during calibrating mathematical relations. (column 9, lines 44-53 of Mills). It is known in the art that calibration using human subjects are performed when determining a computation model for an optical diagnostic device. It is also well known in the art that the required accuracy of the model and the availability of subjects are factors to determining when determining calibration procedures. This information provides a clear suggestion that the number of subjects can be modified and that the determination of the most appropriate number of subjects by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills (cited by Applicant) as applied to claim 1 in view of U.S. Patent 5,800,347 to Skates et al. Mills does not explicitly teach of providing a population comprising a sufficient number of subjects to establish a category selector in which the number of subjects comprises a sub-population of humans in a disease state and a sub-population of humans not in a disease state. Mills teaches the use of normal volunteers during calibrating mathematical relations. (column 9, lines 44-53 of Mills). Mills implies that such calibration using human subjects is used when determining a

computation model for an optical diagnostic device. It is also well known in the art that the required accuracy of the model and the availability of subjects are factors to determining when determining calibration procedures. One method of establishing mathematical relations from calibration is using a statistical analysis of measurements on normal and diseased populations to establish multivariate algorithms. (Abstract of Skates et al.). Such multivariate algorithms are used to establish measurement thresholds to aid in diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold. (column 4, lines 16-53 of Skates et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the calibration method as disclosed by Skates et al. in the method and apparatus of Mills since multivariate algorithms are used to establish measurement thresholds to aid in diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold.

Response to Arguments

6. Applicant's arguments filed on 9/3/2002 have been fully considered but they are not persuasive. The Applicant contends that Mills does not teach at least one optical property is measured at a first area on a body part of a human subject using a first temperature program and another optical measurement on a second area of the body part which is morphologically similar, adjacent, but not substantially overlapping with a second temperature program. The Examiner respectfully disagrees. The Examiner

interprets the language of the claims more broadly than the Applicant. Figs. 5b and 5c clearly show that the optical measurements are taken on a body part, i.e. the hand. Figs. 5b and 5c also show that the optical measurements are taken on adjacent areas that are morphologically similar, i.e., adjacent fingers. Using this interpretation of the meaning of the claim terms, Mills anticipates the invention disclosed in the present application.

7. Applicant's arguments with respect to claim 8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 7:30 a.m. - 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eric Winakur can be reached on 703-308-3940. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and 703-308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Matthew Kremer
Assistant Examiner
Art Unit 3736
November 7, 2002



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